Remarks

Upon entry of the foregoing amendment, claims 2, 3, 6, 8 and 11-15 are pending in the application,.

Support for the amendment to claim 11 is found, *inter alia*, at specification page 4, first paragraph. These changes are believed to introduce no new matter, and their entry is respectfully requested. These changes are believed to place the application in condition for allowance, or otherwise lesson the issues for appeal. Accordingly, entry of these amendments after final is believed proper.

Objection to claim 11

Examiner objects to claim 11 as not ending in a period. Applicants have amended claim 11 to end in a period. Accordingly, this objection can be withdrawn.

The Rejection under 35 U.S.C. § 112, First Paragraph (Written Description)

At Office action paragraph 9, claims 11-15 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Applicants respectfully traverse this rejection and request reconsideration.

Examiner states that the specification does not contain a written description of the treatment and prevention of a disease related to diabetes other than those disclosed in the

first paragraph on page 4. Applicants have amended claim 11 to refer to the diseases referred to in the first paragraph on specification page 4. Accordingly, it is believed that this rejection can be withdrawn.

The First Rejection under 35 U.S.C. § 103

At Office Action paragraphs number 13, claims 2, 3, 6 and 8 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Dittrich *et al., Phytochemistry 11*:245-250 (1971) in view of Sultana *et al., Phytochemistry 50*:1249-1253 (1999) or Pagé (US 6,002,025). Dittrich is relied on as teaching that the compound 5-O-methyl-myo-inositol (sequoyitol) is found in the Taxaceae class and family of plants. However, the Examiner states that Dittrich does not teach a method of extracting the compound from the plants.

The Examiner states that the steps and solvents disclosed in the claims are well known and are taught by Sultana and by Pagé. The Examiner states that one of ordinary skill in the art at the time the invention was made would have found it obvious to extract the compound sequoyitol from the Taxaceae class and family of plants as disclosed in Dittrich by using well known steps and solvents such a those taught by Sultana and Pagé.

Applicants respectfully traverse this rejection and request reconsideration.

The procedure of the present invention for isolation and purification of sequoyitol used macroporous resin chromatography as the key step and provide a method that is functional in large scale. The procedures of sequoyitol's isolation that are described in

the prior art were not optimized for large scale production. Rather they were performed only in much smaller scales for laboratory assays.

The Examiner states that although Sultana and Pagé do not disclose that their columns are macroporous, nevertheless, one skilled in the art at the time the invention was made would have found it obvious to utilize a column having the pore size necessary for obtaining the desired separation. However, this conclusion is unsupported.

Applicants disclosed the antidiabetes bioactivity of sequoyitol for the first time. This property was not previously known. Accordingly, there is no motivation in the combination of the cited art to reach a large scale production method for sequoyitol, much less to arrive at Applicants' specific production method.

The arguments above demonstrate that the claimed method is not suggested by the combination of the cited art. Accordingly, *prima facie* obviousness is not established and this rejection can be withdrawn.

The Second Rejection under 35 U.S.C. § 103

At Office Action paragraphs number 14, claims 11-14 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Ostlund (US 5,550,166) in view of Dittrich and Oberley (*Free Radic. Biol. Med. 5*:113-124 (1988).

Ostlund is relied on as teaching the compound pinitol, compositions containing pinitol and its use in the treatment of diabetes. Dittrich is relied on as teaching that pinitol is a stereoisomer of sequoyitol. Oberley is relied on as teaching that not only are

oxygen radicals involved in the cause of diabetes but alsot hat they appear to play a role in some of the complications seen in long-term treatment of diabetes.

The Examiner states that one of ordinary skill in the art at the time the invention would reasonably expect that based upon the teachings of Oberley, that the treatment of diabetes and its complications in the manner taught by Ostlund et al in view of Dittrich et al would also involve treatment of free radicals which according to Oberley is a cause of diabetes. Applicants respectfully traverse this rejection and request reconsideration.

Sequoyitol and pinitol are different compounds with different stereochemical structures. The stereochemical strutures of inositol's nuclear skeleton are very complicated because there are several chiral carbons in inositols. For example, insitols include *myo*-inositol, *chiro*-inositol, *neo*-inositol, *scyllo*-inositol, *epi*-inositol (see G. P. Moss, Nomenclature of Cyclitols, Recommendations, 1973. (previously submitted).

Sequoyitol belongs to the *myo*-inositols but pinitol is a *chiro*-inositol. Therefore, sequoyitol and pinitol are different compounds with different stereochemical structures.

Compounds that are similar in structure are not always expected to have similar properties. Compounds that are similar in structure may have different activities. For example, the azole nucleoside of D-pinitol and pinitol have the same structural nucleus (chiro-inositol), but the azole nucleoside of D-pinitol has anticancer activity.

Myo-inositol and sequoyitol have the same structural nucleus (*myo*-inositol), but *myo*-inositol has vitamin B complex and lipotropic activities.

BB-pol (polysaccharide fraction extracted from *B. bifidum* BGN4, (FEMS Microbiol. 240:131-136 (2004)) is a composition that comprises *chiro*-inositol,

rhamnose, glucose, galactose and ribose, but it has anticancer activity against HT-29 and HCT-116 cells.

Therefore, the mere fact that pinitol is a stereoisomer of sequoyitol does not create a presumption that if one is useful to treat diabetes the other will be too.

Dittrich and Oberley do not cure the deficiencies of Ostlund. Dittrich and Oberley are silent with regard to whether pinitol and sequoyitol would share this characteristic. The combination of Dittrich and Oberley and Ostlund does not reach the claimed invention, and does not render it *prima facie* obvious. Accordingly, this rejection can be withdrawn.

Conclusion

Prompt and favorable consideration of this amendment and reply is respectfully requested. Applicants believe the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided, or to send an e-mail at the e-mail address provided.

Respectfully submitted,

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Medline Abstract

Anticancerogenic effect of a novel chiroinositol-containing polysaccharide from Bifidobacterium bifidum BGN4.

HJ You, DK Oh, and GE Ji

FEMS Microbiol Lett, November 15, 2004; 240(2): 131-6.

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Strains of bifidobacteria have many health-promotion effects. Whole cells or cytoplasm extracts of Bifidobacterium bifidum BGN4, isolated from human feces, inhibited the growth of several cancer cell lines. The polysaccharide fraction (BB-pol) extracted from B. bifidum BGN4 had a novel composition, comprising chiroinositol, rhamnose, glucose, galactose, and ribose. Three human colon cancer cell lines were treated with BB-pol: HT-29, HCT-116, and Caco-2. Trypan blue exclusion assay and BrdU incorporation assay showed that BB-pol inhibited the growth of HT-29 and HCT-116 cells but did not inhibit the growth of Caco-2 cells.

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- Journal article
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MeSH Terms:

- Antineoplastic Agents
- Bifidobacterium
- Bromodeoxyuridine
- Cell Count
- Cell Line, Tumor
- Cell Proliferation
- Colonic Neoplasms
- Feces
- Galactose
- Glucose

- Humans
- Inositol
- Polysaccharides, Bacterial
- Rhamnose
- Ribose
- Trypan Blue

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